REMARKS/ARGUMENTS

Claims 19-29 and 33-40 are in the application. Claims 19, 33 and 37 have been amended to elaborate on the previous wording therein. These amendments do not narrow the claims nor require additional searching.

I. Claims 19-29

The Examiner rejected claims 19-29 under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. (U.S. Patent No. 5,687,452) in view of Logothetis (U.S. Patent No. 4,521,237).

At the onset, the undersigned would like to thank the Examiner for courtesies extended during the recent telephone interview. As discussed therein, Lawecki et al. is specifically directed to forming an article, such as by molding, with sufficient heat to render the molded article substantially free from contaminants (Column 1, lines 53-58; Column 3, lines 35-41). If insufficient heat is provided during molding, internal surfaces of the molding isolation module 12 are to be periodically sterilized, such as with sterilizing gas or vapor (Column 3, lines 43-48; Column 8, lines 30-45). To prevent contaminants from settling on the clean surfaces of the molded articles, continuous laminar air flow is provided. (Column 4, lines 23-25; Column 2, lines 18-20; Column 6, lines 49-51). It is clear from the teachings of Lawecki et al. that Lawecki et al. seeks to prepare a product free of contaminants, either by providing sufficient heat at the

time of formation or by using sterilization, and to provide sufficient air flow thereafter to prevent contaminants from settling on the clean surfaces of the prepared products.

With reference to Logothetis, Logothetis specifically requires sterilizing in addition to annealing a glass syringe: "...the syringe is completed by being **annealed, sterilized**, and filled with the desired medicine or dosage." (Column 4, lines 26-28) (Emphasis applied).

As indicated in Column 4, lines 14-21 of Lawecki et al., Lawecki et al. specifically discloses that where forming a product from melted plastic, sufficient heat can be generated to avoid further decontamination. Admittedly, Lawecki et al. discloses that glass is useable in its system at Column 3, lines 41-43. There is, however, no specific disclosure or discussion in Lawecki et al. that sufficient heat can be generated from a glass annealing process to avoid decontamination. Moreover, as pointed out above with respect to Logothetis, Logothetis specifies sterilizing a glass syringe after annealing. Taking a hypothetical combination of Lawecki et al. and Logothetis, a glass syringe barrel can be formed with the apparatus of Lawecki et al., however sterilization is required after formation of the glass syringe barrel. In other words, Lawecki et al. and Logothetis taken together do not disclose that annealing a glass syringe provides sufficient heat to avoid the separate step of sterilization (e.g., gas sterilization); as such, the hypothetical combination requires sterilization after annealing a glass syringe barrel

to prepare the article free from contaminants. It should be further pointed out that neither reference discloses annealing at a specific temperature of at least 500°C.

Claim 19 requires the steps of "annealing said glass syringe barrels at a temperature of at least 500°C" then "immediately transferring said syringe barrels to at least one housing assembly for maintaining a predetermined cleanliness level, without any sterilization between said annealing and said transferring steps." In sum, the hypothetical combination of Lawecki et al. and Logothetis does not provide all of the limitations of claim 19, and, thus, does not provide a prima facie showing of obviousness of claim 19. It is respectfully submitted that claim 19, along with dependent claims 20-29, are patentable over Lawecki et al. and Logothetis, each taken alone or in combination.

II. Claims 33-36 and 37-40

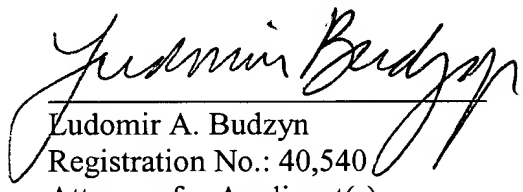
Claims 33-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. in view of AAPA (Applicant Admitted Prior Art). Claims 33 and 37 have been amended to respectively recite the step of "air washing" rather than "air cleaning". Support for this amendment may be found at page 30, line 15 of Applicants' specification. As discussed during the interview, air washing is understood in the art as being a method of removing contaminants

from the surface of an article. (See, e.g., Column 5, lines 25-34 of U.S. Patent No. 5,597,530 to Smith et al.). Specifically, in the context of claims 33 and 37, tip caps are air washed.

As acknowledged by the Examiner at page 7 of the November 21, 2003 Office Action, any tip caps used in Lawecki et al. are formed in additional manufacturing modules that are provided. Furthermore, as discussed above, Lawecki et al. requires articles to be manufactured clean with that cleanliness maintained. The laminar air flow provided in Lawecki et al. is to prevent contaminants from settling on an article, rather than affirmatively cleaning such surfaces. (See, Column 1, lines 56-58; Column 2, lines 12-14; Column 4, lines 23-25). There is simply no disclosure in Lawecki et al. to provide air washing of tip caps. Moreover, there is no suggestion to modify Lawecki et al. to include such. In particular, Lawecki et al. desires avoidance of all additional washing and decontamination steps beyond manufacturing. (Column 2, lines 38-42; Column 4, lines 17-21; Column 8, lines 56-58). Because of these teachings, there is no motivation to modify Lawecki et al. to include air washing of tip caps. It is respectfully submitted that claims 33-40 are patentable over Lawecki et al.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



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